MS9673

PA021SPCA00

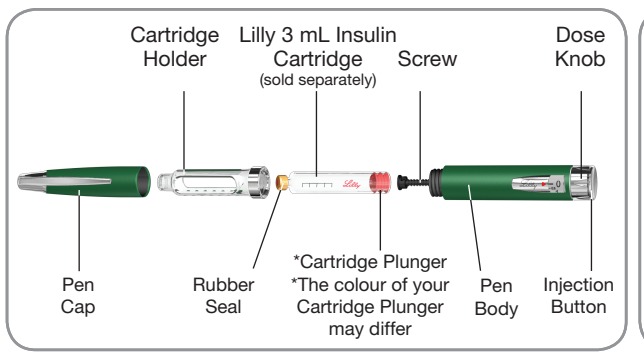
HumaPen LUXURA® HD

INSULIN DELIVERY DEVICE USER MANUAL

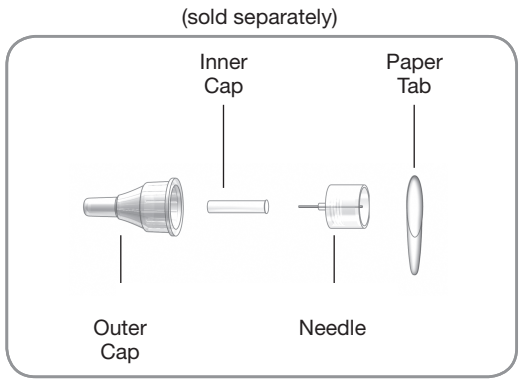
For use only with Lilly insulin (Humalog® or Humulin®) 3 mL Cartridges (100 units/mL). Your HumaPen LUXURA® HD may be a different colour from the one shown, but it will work in the same way.

www.lilly.ca

HumaPen LUXURA® HD Pen Parts



Pen Needle
(sold separately)



HumaPen LUXURA HD is designed to enable you to reliably deliver an accurate dose of your insulin in an easy to use manner. You can inject from 0.5 to 30 units of any Humalog or Humulin insulin from a 3 mL cartridge (100 units/mL). You can dial your dose one half (1/2) unit at a time. If you dial too many units, you can correct the dose without wasting any insulin.

Read this manual completely and follow the directions carefully before using the pen. Failure to follow the instructions may result in too much or too little insulin being delivered.
DO NOT SHARE YOUR PEN OR NEEDLES AS THIS MAY RISK TRANSMISSION OF INFECTIOUS AGENTS.
If any of the parts of your HumaPen LUXURA HD appear broken or damaged, DO NOT USE. Contact your healthcare professional or call Lilly at 1-888-545-5972 for a replacement pen. HumaPen LUXURA HD is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it. Always carry a spare source of insulin that you are trained on how to inject and could immediately use in case your pen is lost or damaged.

1 INSERT THE INSULIN CARTRIDGE

Important Notes

- Your healthcare professional has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.
- **HumaPen LUXURA HD is for use only with Lilly insulin (Humalog or Humulin) 3 mL cartridges.**
- **Do not use other brands of insulin cartridges.**
- Read and follow the instructions provided in your Humalog or Humulin 3 mL insulin cartridge Consumer Information Leaflet.
- Before each injection, read the cartridge label and be sure the pen contains the correct Humalog or Humulin 3 mL insulin cartridge.
- The colour of the pen is not intended to indicate insulin type.
- The numbers on the cartridge holder give an estimate of the amount of insulin remaining in the cartridge. Do not use these numbers for measuring an insulin dose.
- For more information on HumaPen LUXURA HD and Humalog or Humulin insulin, please contact your healthcare professional or Lilly at 1-888-545-5972 or visit our website at www.lilly.ca.

Frequently Asked Questions about Inserting the Insulin Cartridge

1. Why doesn't the screw move out when there is no cartridge in the pen?

The screw may not move out when you push the injection button unless there is a cartridge in the pen. This feature of the pen allows you to easily push the screw into the pen body when replacing a cartridge. Once a cartridge is inserted, the screw will move out when the injection button is pushed.

2. What should I do if I can't attach the cartridge holder to the pen body?

Check that the insulin cartridge is fully inserted into the cartridge holder. Then carefully line up the cartridge holder with the pen body and screw together until secure.

2 PRIME THE PEN BEFORE EVERY INJECTION

Important Notes

- HumaPen LUXURA HD is recommended for use with BD Pen Needles.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.
- Do not store your pen with the needle attached. Use a new needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce needle clogs.

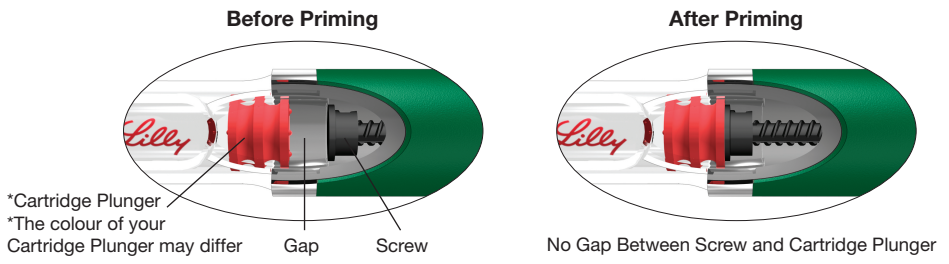
Frequently Asked Questions about Priming

1. Why is it important to prime before every injection?

If you do NOT prime, you may get too much or too little insulin. Priming helps to ensure that the pen and needle are working properly. Once the pen is properly primed, a stream of insulin will flow from the needle. You may need to prime several times before you see a stream of insulin.

2. Why can it take several attempts to prime when a new cartridge is inserted?

There may be a gap between the screw and the cartridge plunger. Repeating the priming steps will move the screw out to touch the cartridge plunger. Once the end of the screw pushes the cartridge plunger out, insulin will flow from the needle.



- Repeat the priming steps until a stream of insulin is seen.
- If you are still unable to see a stream of insulin flow from the needle, go to Question 3.

3. Why should I prime to a stream, and why isn't the pen ready for use if I see a drop of insulin on the needle tip?

Priming moves the screw into contact with the cartridge plunger and gets the air out of the cartridge. When you are priming the pen:
- You may see a drop of insulin on the tip of the needle when you first attach it. This only shows that the needle is attached and not clogged. You must still prime the pen.
- You may also see no flow at all. This may be because the screw is moving forward to close a gap between the screw and the cartridge plunger.
- If there is air in the cartridge, the insulin may sputter or drip until all the air is removed.
- Insulin will flow as a stream only when the pen is properly primed.
- If the injection button is hard to push, the needle may be clogged. Attach a new needle. Repeat the priming steps until a stream of insulin is seen.

If you are still unable to see a stream of insulin out of the needle, **do NOT use** the pen. Contact your healthcare professional or Lilly at 1-888-545-5972 for assistance or to obtain a replacement.

4. What should I do if I have an air bubble in the cartridge?

Priming your pen will remove air bubbles. Point the pen up, and tap the cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until a stream of insulin is seen. A small air bubble may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, this small air bubble will not affect your insulin dose.

3 INJECT THE DOSE

Important Notes

- You must **PUSH** the injection button straight down for the dose to be delivered.
- You will **NOT** receive your insulin by turning the dose knob.
- Do not attempt to change the dose while injecting.

Frequently Asked Questions about Injecting

1. Why is it difficult to push the injection button when I try to inject?

- Your needle may be clogged. Try attaching a new needle, and then prime the pen.
- Pushing the injection button down quickly may make the button harder to push. Pushing the button more slowly may make it easier.
- Using a larger diameter needle will make it easier to push the injection button during injection. See your healthcare professional to determine which needle is best for you.

If none of the above steps resolves the problem, your pen may need to be replaced.

Your injection button may become harder to push if the inside of your pen gets dirty with insulin, food, drink or other materials. Following the CARE AND STORAGE instructions below should prevent this.

2. Why doesn't the dose knob go to zero when I inject my dose?

This can happen if the insulin cartridge does not have enough insulin left in it for your entire dose. The number in the dose window is the amount you did **NOT receive**. To get the rest of your dose, remove the needle, change the insulin cartridge, attach a new needle and prime the pen. Then complete your dose by dialing the amount that you did **NOT receive** and inject only this amount.

3. Why is insulin leaking from the needle after I finish my dose?

You may have removed the needle from your skin too quickly; remember to push and hold the injection button and **slowly count to 5** before removing the needle. Make sure you see a 0 in the dose window to confirm you received the complete dose.

CARE AND STORAGE

- Remove the needle after every use. Do not store the pen with the needle attached.
- Keep the pen away from moisture, dust, extreme hot or cold temperatures, and direct sunlight.
- **Do not store the pen in a refrigerator.**
- Wipe the pen cap, pen body and case with a damp cloth to clean them.
- Do not use alcohol, hydrogen peroxide or bleach on the pen body or dose window. Also, do not cover in liquid or apply lubrication such as oil, as this could damage the pen.
- Refer to the insulin cartridge Consumer Information Leaflet for complete insulin storage instructions.

REPLACEMENT

Your HumaPen LUXURA HD has been designed to be used for up to 3 years after first use. Record the date your pen was first used here: __/__/__. Go directly to a pharmacy to get a new HumaPen LUXURA HD when your pen has been used for 3 years.

USE AS DIRECTED

HumaPen LUXURA HD should only be used as described in this manual. The manufacturer will not be responsible for any problems with the device if these instructions are not followed. Failure to follow the instructions may result in breakage of the pen and too much or too little insulin being delivered.

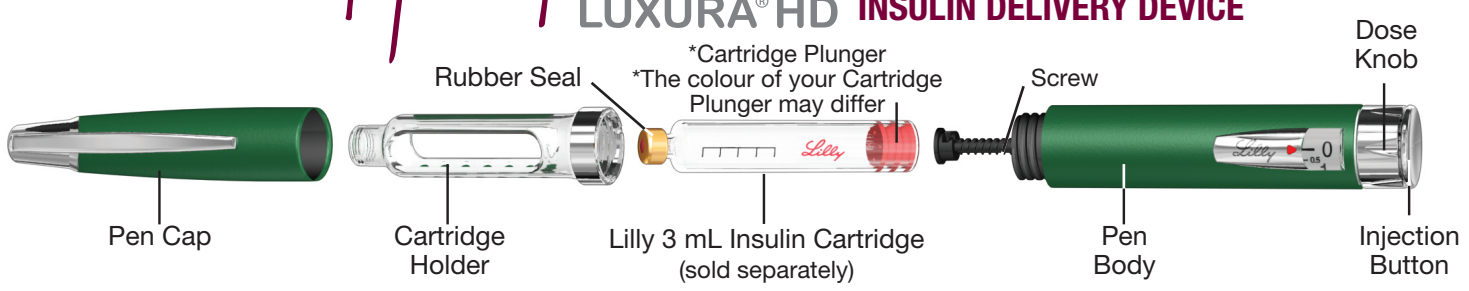
If you have any questions or concerns with your HumaPen LUXURA HD, contact your healthcare professional or Lilly at 1-888-545-5972 for assistance.

Getting Ready

Wash your hands and make sure you have the following items before beginning:

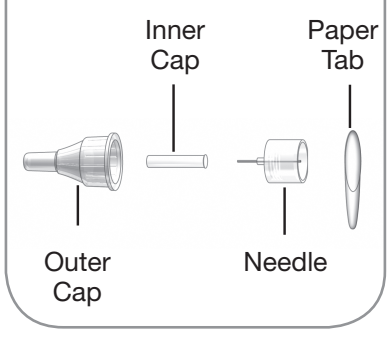
- HumaPen LUXURA HD
- Humalog or Humulin 3 mL Insulin Cartridge
- New Pen Needle
- Alcohol Swab

HumaPen LUXURA® HD INSULIN DELIVERY DEVICE



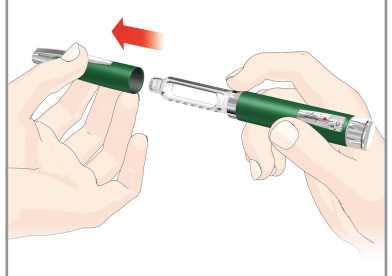
HumaPen LUXURA HD Pen Parts

Pen Needle (sold separately)

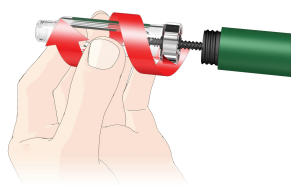


1 INSERT THE INSULIN CARTRIDGE

Pull Off Cap

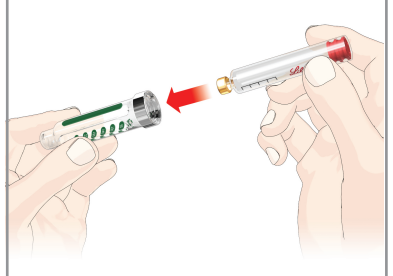


Unscrew Cartridge Holder



A

Insert Cartridge



Insert small end of Humalog or Humulin 3 mL insulin cartridge into the cartridge holder.

Note:

Before inserting, check the insulin cartridge to make sure it is not cracked or broken.

B

Push Screw Back

- The screw may be in or out when you get the pen.
- If the screw is out, use the cartridge plunger to push the screw back.

Note:

If you push the injection button without a cartridge in the cartridge holder the screw will not move forward.

C

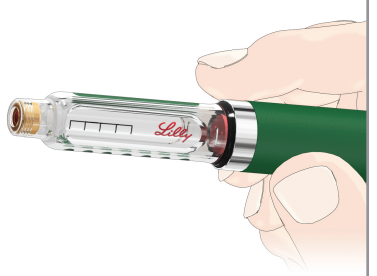
Attach Cartridge Holder

Push the cartridge holder and pen body straight together. Screw the pen body onto the cartridge holder until it is secure.

Caution: If the cartridge holder is not completely attached, the screw may not move and you may not get your full dose.

D

Inspect Insulin



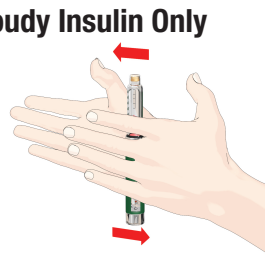
Be sure to check your insulin for:

- Type
- Expiration date
- Appearance

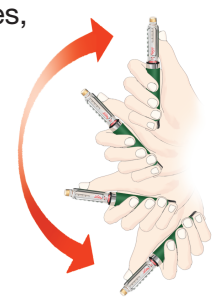
Wipe the small rubber seal on the end of the cartridge with an alcohol swab.

E

For Cloudy Insulin Only



Roll the pen gently 10 times,



and invert the pen 10 times. The insulin should look evenly mixed.

F

2 PRIME THE PEN BEFORE EVERY INJECTION

Caution: If you do **NOT** prime, you may get too much or too little insulin.

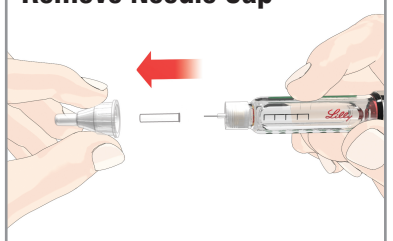
Remove Paper Tab

Attach Needle

Screw needle **straight** onto the cartridge holder.

A

Remove Needle Cap



Pull off the outer cap and the inner cap.

Keep the outer cap to remove the needle after your injection.

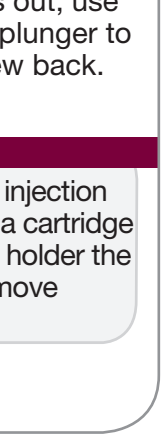
B

Dial 2 Units

Tap Cartridge

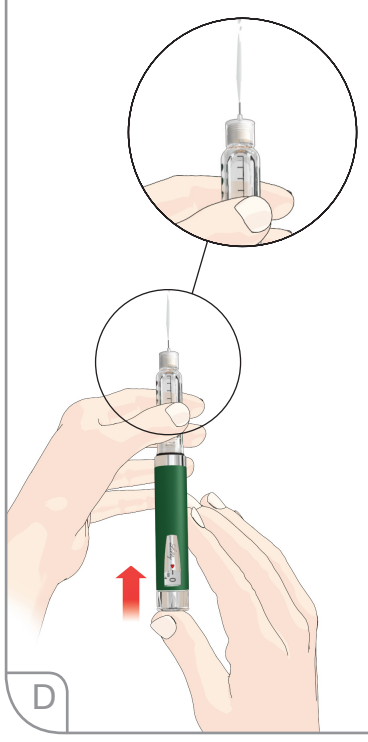
Point pen up.

Tap cartridge to collect air bubbles at the top for removal.



C

Prime The Pen



Push injection button and hold for 5 seconds.

Look for a **stream** of insulin.

The pen is **NOT** properly primed if you only see a few drops of insulin.

Caution: Several attempts to prime may be needed the first time a cartridge is used. If no insulin flows after several attempts the needle may be clogged and should be replaced.

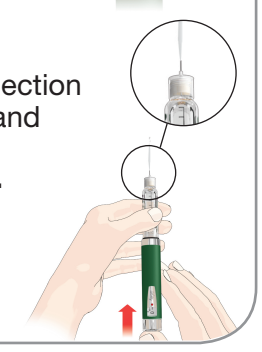
D

If No Stream Is Seen, Repeat Priming

Dial 2 units.

Tap cartridge.

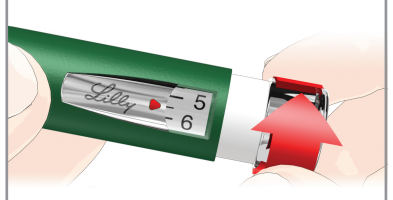
Push injection button and look for **stream.**



E

3 INJECT THE DOSE

Dial Your Dose



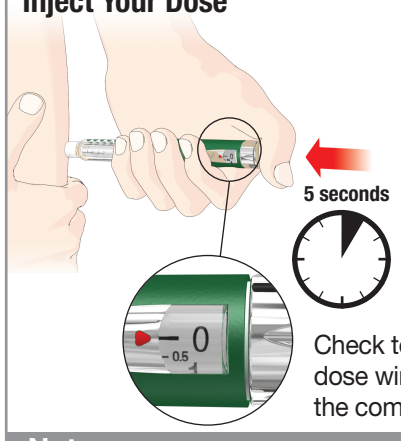
Turn dose knob to your desired dose.

Example: 5½ units shown in the drawing above.

If you dial too many units, you can correct the dose by dialing backwards.

A

Inject Your Dose



Insert the needle as directed by your healthcare professional.

Place your thumb on the injection button then **slowly** and firmly push the button until it stops moving.

Continue to hold the button for **5 seconds**, then remove the needle from your skin.

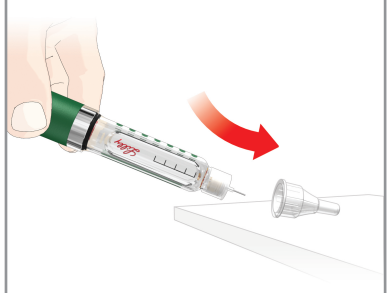
Check to make sure you see a **0** in the dose window to confirm you received the complete dose.

Note:

It is possible to set a dose larger than the amount of insulin left in the cartridge.
At the end of an injection, the number in the window should be **0**.
If it is not, this is the amount of insulin you did **NOT receive**.
Remember this number.
Remove the needle and the empty cartridge.
Insert a new cartridge as shown in (1), and prime the pen as shown in (2).
Complete your dose by injecting only the amount you did not receive.
If you do not think you received your full dose, do not take another dose. Call your healthcare professional or Lilly at 1-888-545-5972 for assistance.

B

Replace Needle Outer Cap



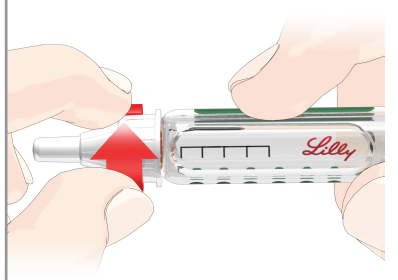
Carefully replace the outer cap as instructed by your healthcare professional.

Note:

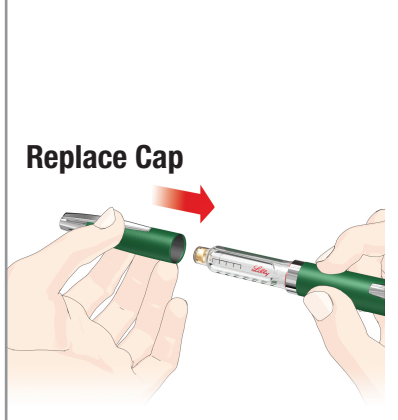
To prevent air from entering the cartridge, do not store the pen with a needle attached.

C

Remove The Needle



Replace Cap



- Remove the capped needle by twisting it off.
- Put used needles in a closable, puncture-resistant sharps container (like a biohazard container).
- Do not recycle the filled sharps container.
- Ask your healthcare provider about options available in your area to throw away the sharps container properly. You can also check the Canadian Diabetes Association website at www.diabetes.ca for information on sharps disposal.
- The directions regarding needle handling are not intended to replace local, healthcare provider or institutional policies.

D

If you have any questions or concerns with your HumaPen LUXURA HD or require further assistance, contact your healthcare professional or Lilly at 1-888-545-5972.

Distributed by:
Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario
M1N 2E8

Manufactured by:
Eli Lilly and Company
Pharmaceutical Delivery Systems
Lilly Corporate Center
Indianapolis, IN 46285, USA

Authorized Representative in the EU:
Eli Lilly and Company Ltd.
Erl Wood Manor, Windlesham, Surrey
GU20 6PH UK

HumaPen LUXURA HD meets the current dose accuracy and functional requirements of ISO 11608-1:2000 with Lilly 3 mL cartridges.

CE 0344

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Document Revision Date: July 3, 2013

PA021SPCA00